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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LARRY CALDWELL and BRADLEY GALER

Appeal 2009-006342
Application 10/029,408
Technology Center 1600

Decided: November 30, 2009

Before DONALD E. ADAMS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges.*

LEBOVITZ, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal from the Patent Examiner's rejection of claims 1-19 and 24-40 under 35 U.S.C. § 103(a). Jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are drawn to methods of ameliorating symptoms of carpal tunnel syndrome ("CTS"), a condition which is "caused by pressure exerted on the median nerve at the wrist." (Spec. 1:9-10.)

Claims 1-19 and 24-40 are pending and stand rejected as follows:

- Claims 1-3, 5-8, 10-12, 14-18, 29, 34-36, 38, and 39 under 35 U.S.C. § 103(a) as obvious over Bockow (US 5,709,855, issued Jan 20, 1998) and Edwards (5,989,559, issued Nov. 23,1999) (Ans. 3);

- Claims 4, 9, and 13 under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, and Hirano (US 5,869,087, issued Feb. 9, 1999) (Ans. 5);

- Claim 19 under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, and Shudo (US 2002/0176886 A1, published Nov. 28, 2002) (Ans. 7);

- Claims 24-28 under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, Hirano, and a bandage (Ans. 9); and

- Claims 30-33, 37, and 40 under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, and Liebschutz (WO 02/22109 A2, issued Sep. 17, 2001) (Ans. 11).

As Appellants have argued many of the claims separately, we reproduce independent claim 1 as representative and refer to the claim appendix (pgs. 34-38) of the Appeal Brief for the other claims at issue in this appeal. Claim 1 reads as follows:

1. A method for at least ameliorating a symptom associated with pressure applied to the median nerve of the carpal tunnel of a host, said method comprising:

topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface of said subject proximal to said carpal tunnel;

to ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel of said host.

STATEMENT OF THE ISSUES

Appellants contend that the Examiner erred in:

- combining the Bockow and Edwards publications;

- concluding that the claimed amounts of NSAID were obvious;

- concluding that that the recited symptoms would have been expected to have been ameliorated as claimed and for the recited periods of time;

- concluding that a patch with a hydrogel adhesive and polyester backing would have been obvious; and

- concluding that a topical formulation with an NSAID as the only active agent would have been obvious.

PRINCIPLES OF LAW

"Obviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

When there is a range disclosed in the prior art, and the claimed invention overlaps or falls within that range, there is a presumption of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Iron Grip Barbell Co. v. USA Sports*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

> The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other

> variable within the claims. These cases have consistently held that in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990). (Internal citations omitted.)

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products.

In re Best, 562 F.2d 1252, 1255 (CCPA 1977) (footnote omitted).

Thus, once "the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

> "[W]hen a prima facie case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability." *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is "merely a showing of facts supporting the opposite conclusion." *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

In re Sullivan, 498 F.3d 1345, 1351 (Fed. Cir. 2007).

> [C]ase law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention. "[T]he question is whether there is something in the prior art as a whole to suggest the desirability, and thus the

> obviousness, of making the combination," not whether there is something in the prior art as a whole to suggest that the combination is the most desirable combination available. *See In re Beattie*, 974 F.2d at 1311 (internal quotation omitted; emphasis added). . . . [A] finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed by the patent applicant is the preferred, or most desirable, combination.

In re Fulton, 391 F.3d 1195, 1200 (Fed. Cir. 2004).

"[A] reference may teach away from a use when that use would render the result inoperable." *In re ICON Health and Fitness Inc.*, 496 F.3d 1374, 1381 (Fed. Cir. 2007).

OBVIOUSNESS OVER BOCLOW AND EDWARDS

Claims 1-3, 5-8, 10-12, 14-18, 29, 34-36, 38, and 39 stand rejected under 35 U.S.C. § 103(a) as obvious over Bockow and Edwards (Ans. 3).

Scope and content of the prior art

The Bockow patent

1. Bockow describes compositions for preventing or treating inflammation or pain by topically administering a composition to a surface of the patient's body which is to be treated (col. 2, ll. 48-50; col. 6, ll. 4-7).

2. The composition comprises therapeutically effective amounts of an omega fatty acid and spirulina (col. 2, ll. 50-55).

3. The composition "may optionally comprise a cyclooxygenase inhibitor," such as indomethacin, diclofenac, ibuprofen, and ketoprofen, in amounts effective to treat inflammation (col. 5, ll. 23-43).

4. The inhibitor is optionally present in an amount ranging from 3% to 25% by weight (col. 6, ll. 40-42).

5. The composition can be topically administered in various forms, including as liquids, gels, and creams (col. 6, ll. 10-14; col. 7, ll. 15-18). An occlusive dressing may be further applied over the composition to enhance efficiency (col. 7, ll. 20-22).

6. The composition can be applied 1 to 4 times daily (col. 7, ll. 19-20

7.

> The composition of the present invention may be used to prevent or treat a variety of musculoskeletal conditions, both inflammatory and non-inflammatory in nature, and acute, subacute or chronic presentation. For example, the composition may be used in the treatment of both the early and late stages of inflammatory arthritis, as well as non-infectious inflammatory arthropathy such as rheumatoid arthritis, bursitis, tendinitis, soft tissue injuries, Sjogren's syndrome, systemic lupus erythematous, psoriatic arthritis, gout and other crystalline arthropathies, capsulitis, carpal tunnel syndrome, myositis, polymyalgia, rheumatica, synovitis and Reiter's syndrome. The compositions of this invention may also be used in the prevention or treatment of erosive osteoarthritis.

(Col. 6, ll. 52-65.)

Edwards

8. Edwards teaches a banana peel extract for treatment of arthritis, inflammation, sunburn, and other conditions (col. 1, ll. 42-46).

9. Edwards describes application of a banana peel extract cream to the wrist of an individual "suffering from carpal tunnel syndrome" (col. 8, ll. 18-22).

10. "After she applied extract cream to her right wrist, the swelling and the pain subsided, and the feeling returned to her hand." (Col. 8, ll. 20-22.)

Differences between the prior art and the claimed invention

11. Claim 1 is to a method a method of ameliorating symptoms of CTS comprising "topically administering an effective amount of a topical NSAID formulation to a palmar dermal surface of said subject proximal to said carpel tunnel."

12. Bockow describes treating CTS with an NSAID (F1-3 & 7) as in claim 1, but does describe applying the NSAID to the palmar dermal surface as claimed.

Reason to combine

13. The Edwards patent was cited by the Examiner "as a teaching reference to show that" it was "commonly known in the prior art to apply a topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome." (Ans. 4; F9-10.)

14. Based on Edwards' teaching, the Examiner reasoned that it would have been obvious to persons of ordinary skill in the art to have applied Bockow's NSAID formulation to the painful site at the dermal palmar area as taught by Edwards in order to effectively treat CTS pain (Ans. 4).

Analysis

Claims 1-3, 5-8, 10-12, 14-18, and 35 (Group I)

No apparent reason to combine Bockow and Edwards

Appellants contend that the Examiner improperly combined Bockow's teachings with those of Edwards (App. Br. 8). Appellants assert that the Examiner's rationale is based on an incorrect assumption that CTS is a musculoskeletal disorder (*id.* at 9). According to Appellants, the skilled

worker would have recognized that Bockow incorrectly identified CTS as a musculoskeletal disorder (*id.*). Rather, Appellants argue, and provide supporting evidence[1] to establish that CTS is a neuropathy which is treated with different drugs and has a distinct pathology from musculoskeletal disorders (*id.* at 10; Reply Brief 3-4). "Therefore," Appellant urges, "one of ordinary skill in the art would not have read Bockow as teaching anything with respect to CTS." (App. Br. 11.)

We have no doubt that CTS is not strictly classified as a musculoskeletal disorder, as testified by Dr. Bradley Galer, a co-inventor of the instant application (1st and 2nd Galer Decs.). However, the question still remains as to whether a person of ordinary skill in the art would have believed Bockow's statement that the Bockow composition, with an NSAID, could be utilized to treat carpel tunnel syndrome.

Dr. Galer testified in his declaration that the skilled worker would have approached the treatment of neuropathic conditions differently from how he approach musculoskeletal disorders because the underlying pathologies of the conditions are different (1st Galer Dec. 6; 2nd Galer Dec. 3). This opinion is supported by the facts. Nonetheless, the Specification acknowledges that NSAIDs were a known treatment option for CTS (Spec. 2:13-16). Therefore, Bockow's suggestion that a composition containing an NSAID would be useful to treat CTS would not have been disbelieved by the skilled worker. Rather, it appears that, despite the differences between

[1] Declaration by Dr. Bradley Galer, co-inventor of the application, dated June 2, 2005 ("1st Galer Dec."); Declaration by the same Bradley Galer, dated May 9, 2007 ("2nd Galer Dec.").

the conditions, NSAIDs were known in the art to have been useful for treating both CTS and musculoskeletal disorders.

Another reason that Appellants give for disregarding Bockow's statement that CTS would benefit from its compositions is that Bockow misclassified CTS as a musculoskeletal disorder. However, Appellants' own Specification teaches that tissue swelling in the area of the carpal bone tunnel can cause compression of the median nerve, producing CTS (Spec. 1). Therefore, while CTS pain may arise from direct trauma and dysfunction to the medial nerve (2nd Galer Dec. 3), it is not unreasonable to have described CTS as "musculoskeletal disorder" because of the involvement with the carpel bones and tunnel – components of the skeletal system. Nor would it have been unreasonable to treat CTS with Bockow's anti-inflammatory compositions for those CTS occurrences which involve swelling in the carpel tunnel region.

Finally, there is no statement by Dr. Galer that Bockow's disclosure that its anti-inflammatory composition could be used to treat CTS would not have been credible to the person of ordinary skill in the art.

Persons of ordinary skill in the art would not have predicted success

Appellants contend that "one of ordinary skill in the art would not have predicted success in the effective delivery of an NSAID formulation to the median nerve inside the carpal tunnel upon topical application to a palmar dermis." (App. Br. 13.) Appellants argue that it would not have reasonably been expected that an active agent, when topically applied, would penetrate to the targeted nerve because it is buried behind a thickened

sheath (*id.*) A declaration is provided by Dr. Larry Caldwell ("Caldwell Dec."), a co-inventor of the instant application, to support this position.

We have considered Appellants' evidence, but are not persuaded that the evidence establishes that the Examiner erred. Despite Dr. Caldwell's opinion about the lack of a reasonable expectation of success, Edwards explicitly taught an example in which "the swelling and the pain subsided" after a subject with CTS was treated with topical banana peel cream on the wrist (F10). The Examiner reasonably relied upon this teaching in making the obviousness determination. Dr. Caldwell did not identify a defect in the Examiner's reasoning nor in the Edwards' example. In our opinion, the Examiner's evidence of an actual working example in which a topical active agent was effective in treating CTS outweighed Dr. Caldwell's speculation that it would not have been expected to work.

Dr. Caldwell also testified that "it was not at all certain that a sufficient amount of a given active agent would penetrate deeply enough to reach the target site." (Caldwell Dec. ¶ 6). Dr. Caldwell did not base this opinion on the proper obviousness standard. It is well-established that absolute predictability is not needed to establish obviousness. All that is required is a reasonable expectation of success. *In re O'Farrell*, 853 F.2d at 903-04. Thus, the Examiner did not need to find it "certain" that the NSAID would be effective to ameliorate at least one symptom of CTS. Rather, Edwards' teaching about the efficacy of Edwards' topical banana peel in treating CTS was sufficient to give rise to a reasonable expectation of success that Bockow's topical composition comprising an NSAID would be topically effective for the same purpose.

Claim 29 (Group II)

Claim 29 is to the method of claim 1 in which the NSAID is "in an amount ranging from about 0.1 to about 5%." Appellants contend that the Examiner erred in rejecting the claim by "fail[ing] to provide a specific citation of Bockow or Edwards teaching a formulation" comprising the claimed amount (App. Br. 15). Appellants assert that Bockow discloses an inhibitor in the range of from 3% to 25% by weight "which is much broader than the claimed range" and that none of Bockow's examples treat CTS or neuropathic pain (*id.* at 15).

Facts

15. The claimed range of "about 0.1 to about 5%" overlaps with Bockow's inhibitor range of 3% to 25% by weight (F4).

Analysis

As stated by the Examiner, it "would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as decreasing pain." (Ans. 16). Having established the existence of overlapping ranges (F15) and the routine skill involved in choosing an effective range, the burden properly shifted to Appellants to show that their invention would not have been obvious. *In re Peterson*, 315 F.3d at 1329 (Fed. Cir. 2003); *In re Woodruff*, 919 F.2d 1578. As Appellants have provided no rebuttal evidence, we affirm the rejection for the reasons set forth by the Examiner.

Claim 34 (Group III)

Claim 34 is an independent claim drawn to a method for treating a subject for neuropathic symptoms associated with CTS comprising topically applying an NSAID. In addition to the reasons that the combination of Bockow and Edwards did not render the subject matter of claim 1 obvious, Appellants further argue that Bockow does not disclose treating neuropathic symptoms as required by claim 34 (App. Br. 17). We affirm the rejection for the Examiner's well-stated reasons on pages 16-17 of the Answer.

Claim 36 (Group IV)

Claim 36 indirectly depends on claim 1 and further requires that the host "suffers from all of tingling, numbness and pain and said method ameliorates all of tingling, numbness and pain." Appellants argue that neither Bockow nor Edwards teach ameliorating all of these symptoms (App. Br. 17). In response to the Examiner's statement that the claimed limitations are "inherent" because they would have been met by following Bockow, Appellants' assert that evidence "must" be provided "that the element necessarily flows from the teachings of the prior art reference." (App. Br. 18).

Appellants have not invoked the proper legal standard. The PTO does not have the ability "to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d at 1255. Thus, once "the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d at 708. In this case, the Examiner had sound basis for believing that Bockow's method would ameliorate the claimed symptoms

because "the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference." (Ans. 18.) Appellants have not provided evidence to doubt the Examiner's conclusion or that following Bockow's method would not have resulted in the claimed effect.

Claim 38 (Group V); Claim 39 (Group VI)

Claim 38 indirectly depends on claim 1 and further recites that "at least one symptom is ameliorated for a period of 1 week or longer following application of said topical NSAID formulation." Claim 39 depends on claim 38, and further requires that the symptom is ameliorated for a period of several weeks or longer.

The Examiner found that "the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claim" and Bockow (Ans. 19-20). Therefore, because there was no difference in the manipulative steps, the Examiner found it reasonable to conclude that administering a topical NSAID as taught by Bockow would result in ameliorating pain for the claimed period of time (*id.*).

Appellants assert that Bockow teaches that the "amelioration of the symptoms of a musculoskeletal disorder lasts only up to 24 hours because it teaches application of its formulations 1-4 times daily (col. 7, lines 15-24)" (App. Br. 20) and that such "a surprising finding does not necessarily flow from the teachings of the prior art" (*id.* at 21).

Appellants' arguments do not convince us that the Examiner erred. First, since the evidence established that Bockow discloses treating CTS

with a formulation comprising an NSAID, the Examiner reasonably concluded that such treatment regime – which is indistinguishable from the claimed method – would ameliorate symptoms for one week or longer as claimed. As such effect would have been a consequence of following Bockow, it is unnecessary that persons of ordinary skill in the art would have recognized the claimed benefit. Secondly, Bockow does not teach that the ameliorating effect of its compositions only last only up to 24 hours as asserted by Appellants (App. Br. 20-21). Although Bockow describes daily application of its compositions to the site of inflammation, Bockow does not state that such application regime is necessary to achieve continued relief. In Example 2, Bockow describes the treatment of patients with a formulation that comprises methyl salicylate (col. 9, ll. 24-40; col. 8, l. 62). Bockow states that "88% showed . . . sustained pain relief" (col. 9, ll. 32-34), indicating that prolonged amelioration ("sustained") of symptoms is achieved with the Bockow composition.

Appellants assert that "surprising" results have been obtained with the claimed method, but cited no factual evidence to support their assertion. Accordingly, we do not find Appellants' contentions persuasive.

OBVIOUSNESS OVER BOCKOW, EDWARDS, & HIRANO

Claims 4, 9, and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, and Hirano (Ans. 5).

Claims 4, 9, and 13 are dependent claims, further requiring that the NSAID formulation is a patch. The Examiner cited Hirano for its teaching of a patch (Ans. 10). Appellants did not challenge the pertinence of Hirano. Rather, Appellants contend that the claims are not obvious for the same

reasons as argued for Group I (App. Br. 22). As we did not find these arguments persuasive for claim 1 and others, we do not find them compelling for claims 4, 9, and 13.

OBVIOUSNESS OVER BOCKOW, EDWARDS, & SHUDO

Claim 19 stands rejected under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, and Shudo (Ans. 7).

Appellants contend that the claim is not obvious for the same reasons as argued for Group I (App. Br. 23). As we did not find these arguments persuasive for claim 1 and others, we do not find them compelling for claim 19.

OBVIOUSNESS OVER BOCKOW, EDWARDS, HIRANO, & A BANDAGE

Claims 24-28 stand rejected under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, Hirano, and a bandage (Ans. 9).

Claims 24 and 28 are to methods in which the NSAID is applied by contacting the palmar dermal surface with a hydrogel patch comprising the NSAID. Claims 25-27 depend on claim 24. The Examiner cited Hirano for its teaching of a patch. Appellants did not challenge the pertinence of Hirano, but argued that the claims are not obvious for the same reasons as argued for Group I (App. Br. 22). As we did not find these arguments persuasive for claim 1 and others, we do not them compelling for claims 24-28.

OBVIOUSNESS OVER BOCKOW, EDWARDS, & LIEBSCHUTZ

Claims 30-33, 37, and 40 stand rejected under 35 U.S.C. § 103(a) as obvious over Bockow, Edwards, and Liebschutz (Ans. 11).

Claims 30 and 31 (Group VII)

Claims 30 and 31 require an amount of NSAID from about 0.1% to about 5%, and further recite that the NSAID is disclofenac (claim 30) and in the form of a patch (claim 31). The claimed range overlaps with Bockow's range (F15) and Liebschutz teaches a patch with diclofenac (Ans. 12). Appellants did not challenge these findings. Rather, Appellants contend that the claims are not obvious for the same reasons as argued for Group I and that Liebschutz does not make up for the deficiency (App. Br. 25-26). As we did not find their arguments regarding Bockow and Edwards persuasive for claim 1 and others, we do not find them compelling for claims 30 and 31.

Claim 37 (Group VIII); Claim 32 (Group IX)

Claim 37 recites that the topical NSAID formulation "comprises from about 0.5 to 2% w/w of an active NSAID." Claim 32 recites that 1.3% w/w of diclofenac is present in the patch.

Facts

16. Liebschutz teaches a topical adhesive patch for application of diclofenac in an amount of 1-15% of the total of the patch's matrix layer (p. 2), which overlaps with the claimed range of 0.5 to 2% (claim 37) and encompasses the value of 1.3% (claim 32). The patch was to treat pain and inflammatory conditions (p. 1-2).

17. Liebschutz describes examples in which 2.5% and 3% disclofenac were present in a topical patch (pp. 8-9).

Analysis

When there is a range disclosed in the prior art, and the claimed invention overlaps or falls within that range, there is a presumption of obviousness. *In re Peterson*, 315 F.3d at 1329; *Iron Grip Barbell Co.*, 392 F.3d at 1322. As the claimed amounts overlap with or are encompassed the range described in Liebschutz (F16), we conclude that the Examiner provided sufficient evidence to establish obviousness of claims 32 and 37 and adopt the Examiner's reasoning as our own (Ans. 23-25).

Appellants state that the examples in Liebschutz teach 2.5% and 3%, and therefore persons of ordinary skill in the art would not have chosen amounts "much below" 2.5% as claimed (App. Br. 26-27).

This argument is not persuasive. Appellants did not provide evidence that the disclosure of working examples comprising 2.5% and 3% diclofenac would have led persons of ordinary skill in the art to have doubted the efficacy of the broader described range of 1-15%.

Claim 33 (Group X)

Claim 33 is to patch with "hydrogel adhesive present on a polyester felt backing."

Facts

18. The Specification describes a topical patch which is "marketed . . . in several European countries" which "consist[s] of a hydrogel adhesive spread on a polyester felt backing." (Spec. 10:1-5).

Analysis

The Examiner found the claimed patch obvious in view of Liebschutz and the admission in the Specification that a patch with polyester felt backing was known in the art (F18; Ans. 25-26). Appellants' argument that such elements are lacking from Liebschutz is without merit since the claimed patch was acknowledged to be prior art.

Claim 40 (Group XI)

Claim 40 is to the method of claim 1, where the NSAID is only active agent in the formulation.

Appellants argue that Bockow "teaches away from a topical formulation comprising an NSAID as the only active agent because Bockow's formulation requires the present of an omega fatty acid and spirulina, both as active agents." (App. Br. 30.)

However, Liebschutz explicitly taught the NSAID diclofenac was alone effective in treating pain and inflammatory conditions (F16-17). As a general principle, a "teaching away" from a claimed invention must be considered when making an obviousness determination. *See In re Gurley*, 27 F.3d at 553. However, simply because a product is described as "inferior" in some respects does not by itself constitute a teaching away from using the "inferior" product. *Id.* A teaching that a result would be inferior or less

desirable is not a teaching away unless the use "would render the result inoperable." *In re ICON*, 496 F.3d at 1381. Thus, even if persons of ordinary skill in the art would have considered an NSAID alone to be inferior to Bockow's formulation of an NSAID, a fatty acid, and spirulina, that fact would not have taught away from NSAID as the only active ingredient because the latter still would have been expected to achieve at least some therapeutic effect (FF16-17; Spec. 2:13-16).

SUMMARY

The obviousness rejection of claim 1 is affirmed. Claims 2, 3, 5-8, 10-12, 14-18, and 35 fall with claim 1 because separate arguments for their patentability were not provided.

The obviousness rejections of claim 4, 9, 13, 19, 24-34, and 36-40 are affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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